K020026

SUMMARY OF RAVEN BACTERIAL SPORE STRIPS

JAN 3 0 2002

Submitter:

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Contact:

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President

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Prepared on: January 2, 2002

Device name: Raven Bacterial Spore Strip

Classification: Class II medical device, General hospital

Predicate Devices (legally marketed): Raven Bacterial Spore Strip

Predicate Device 510(k) number: Pre-amendment device

Description:

Raven Bacterial Spore Strip is a 1.5" x 0.25" Schleicher and Schuell #470 cotton paper filter spore strip inoculated with either single species (*B. stearothermophilus* ATCC #7953) or dual species (*B. stearothermophilus* ATCC #7953 and *B. subtilis* ATCC #9372) bacterial spores. The strip is packaged in a #30 blue glassine peel open pouch.

Operational Principles:

The bacterial spore strip is exposed in the glassine pouch to a Steam sterilization cycle (single species *B. stearothermophilus* or dual species. The spore strip is intended for use in determining the efficacy of the sterilization process and should be placed in the most difficult to sterilize area of the load. Upon cycle completion, the spore strip should be removed from the load and aseptically transferred into an appropriate growth media. The media should then be incubated at 55-60°C. Media should be monitored daily for growth and results recorded. When used in conjunction with Raven's Modified Tryptic Soy Broth with Bromocresol Purple, a reduced incubation time for Steam has been validated at 48 hours. Growth will be indicated by a change in color from purple to/towards yellow and/or by turbidity. Detection of a failed sterilization cycle is facilitated by the use of the Raven Bacterial Spore Strip.

Statement of Similarity to Legally Marketed Predicate Device

The Raven Bacterial Spore Strip has the following similarities to the legally marketed Pre-amendment Raven Bacterial Spore Strip.

- Have the same indicated use
- Incorporate the same materials
- Have the same shelf life, and
- Are packaged using the same materials and processes.

Description of Testing:

Per FDA guidance for validation of reduced incubation of biological indicators, testing was performed for the Steam sterilization process using three lots each of newly manufactured spore strips, spore strips nearing expiry, newly manufactured Modified Tryptic Soy Broth with Bromocresol Purple (MTSB w/ BCP) and MTSB w/ BCP nearing expiry. Each combination of new and near expiry strips and media was tested. For all lots tested, 48 hour reduced incubation for Steam sterilization was demonstrated when Raven Bacterial Spore Strips are used in conjunction with Raven's Modified Tryptic Soy Broth with Bromocresol Purple.

Conclusion

The Raven Bacterial Spore Strip is substantially equivalent in composition and function to the Legally Marketed predicate device, Pre-amendment Raven Bacterial Spore Strip, for monitoring Steam sterilization cycles with a reduced incubation period of 48 hours when used in conjunction with Raven's Modified Tryptic Soy Broth with Bromocresol Purple.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Ms. Wendy Royalty-Hann
QA/RA Manager
Raven Biological Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

Re: K020026
Trade/Device Name: Raven Bacterial Spore Strips for Steam Sterilization
Regulation Number: 880.2800
Regulation Name: Biological Indicators
Regulatory Class: II
Product Code: FRC
Dated: January 23, 2002
Received: January 4, 2002

Dear Ms. Hann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications
for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number	K020026
Device Name	Raven Bacterial Spore Strips
Indications for Use	The Raven Bacterial Spore Strip (single species *B. stearothermophilus* ATCC#7953 or dual species *B. stearothermophilus* ATCC #7953 and *B. subtilis* ATCC #9372) is intended for use in testing the efficacy of Steam sterilization cycles at 121°C . A reduced incubation time of 48 hours at 55-60°C has been validated for Steam sterilization when the Raven Bacterial Spore Strip (either the single species *B. stearothermophilus* spore strip or the dual species spore strip) is used in conjunction with Raven's Modified Tryptic Soy Broth with Bromocresol Purple.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020026